

Serial No. 10/032,238

Docket No. 0075.00

In the Claims:

Please amend claims 1-4 and 6-39 as indicated below. Applicants have designated claims 41-43 as being "withdrawn" pursuant to the action taken by the Examiner in Section 1 of the Office Action. Currently amended claims are presented with markings to indicate the changes made, wherein ~~strike through~~ is used to designate deleted subject matter and underlining is used to designate added subject matter.

1. (Currently amended) A ~~spray-dried~~ powder composition comprising ~~IL-4R~~
spray-dried particles comprised of interleukin-4 receptor (IL-4R).
2. (Currently Amended) The ~~powder~~ composition of claim 1, having a monomer content and an aggregate level that is essentially unchanged relative to that of its pre-spray dried solution or suspension.
3. (Currently amended) ~~A storage-stable powder~~ The composition of ~~either~~ claim 1, characterized by a decrease in monomer content as compared to that of its pre-spray dried solution or suspension of not more than 5% when determined after storage of said composition for 14 days at 25°C.
4. (Currently amended) ~~A storage-stable powder~~ The composition of claim 3, characterized by an extent of formation of aggregates as compared to that of its pre-spray dried solution or suspension of not more than 5% when determined after storage of said composition for 14 days at 25°C.
5. (Original) The composition of claim 1, being moisture stable, exhibiting a minimal increase in aggregate formation and a minimal change in monomer content, as compared to the level of aggregate and monomer content of its pre-spray dried solution or suspension, under humid conditions.

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6. (Currently amended) The ~~moisture-stable~~ composition of claim 5, characterized by a decrease in monomer content of not more than 10% when determined after storage of said composition for 14 days at 33% relative humidity.

7. (Currently amended) The ~~moisture-stable~~ composition of claim 5, characterized by a decrease in monomer content of not more than 7% when determined after storage of said composition for 14 days at 33% relative humidity.

8. (Currently amended) The ~~moisture-stable~~ composition of claim 5, characterized by a decrease in monomer content of not more than 5% when determined after storage of said composition for at least 14 days at 33% relative humidity.

9. (Currently amended) The ~~moisture-stable~~ composition of claim 5, characterized by a decrease in monomer content of not more than 5% when determined after storage of said composition for at least 14 days at 75% relative humidity.

10. (Currently amended) The ~~moisture-stable~~ composition of claim 5, characterized by formation of less than 10% insoluble aggregates in water after storage for 14 days at 33% relative humidity.

11. (Currently amended) The composition of claim 1, characterized by formation of less than 7% insoluble aggregates in water upon storage for 14 days at 33% relative humidity.

12. (Currently amended) The composition of claim 1, characterized by formation of less than 5% insoluble aggregates in water upon storage for 14 days at 33% relative humidity.

13. (Currently amended) The composition of claim 1, characterized by formation of less than 5% insoluble aggregates in water upon storage for 14 days at 75% relative humidity.

14. (Currently amended) The composition of ~~claims~~ claim 1, being temperature stable, exhibiting a minimal increase in aggregate formation and a minimal change in monomer content,

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as compared to the level of aggregate and monomer content of its pre-spray dried solutions or suspension, under extreme temperatures.

15. (Currently amended) The ~~temperature-stable~~ composition of claim 14, characterized by a decrease in monomer content of not more than 10% after storage for 14 days at 2 to 8°C or 40 to 50°C.

16. (Currently amended) The ~~temperature-stable~~ composition of claim 14, characterized by a decrease in monomer content of not more than 7% after storage for 14 days at 2 to 8°C. or 40 to 50°C.

17. (Currently amended) The ~~temperature-stable~~ composition of claim 14, characterized by a decrease in monomer content of not more than 5% after storage for 14 days at 2 to 8°C. or 40 to 50°C.

18. (Currently amended) The ~~temperature-stable~~ composition of claim 14, characterized by formation of less than 10% insoluble aggregates after storage for 14 days at 2 to 8°C. or 40 to 50°C.

19. (Currently amended) The ~~temperature-stable~~ composition of claim 14, characterized by formation of less than 7% insoluble aggregates after storage for 14 days at 2 to 8°C. or 40 to 50°C.

20. (Currently amended) The ~~temperature-stable~~ composition of claim 14, characterized by formation of less than 5% insoluble aggregates after storage for 14 days at 2 to 8°C or 40 to 50°C.

21. (Currently amended) The ~~powder~~ composition of claim 1 in aerosolized form.

22. (Currently amended) The ~~powder~~ composition of claim 1 substantially free from ~~excipients~~ excipients.

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23. (Currently amended) The ~~powder~~ composition of claim 1, further comprising at least one pharmaceutically acceptable excipient.

24. (Currently amended) The ~~powder~~ composition of claim 23, wherein the excipient is selected from the group consisting of carbohydrates, amino acids, oligopeptides, peptides, and proteins.

25. (Currently amended) The ~~powder~~ composition of claim 24, wherein said carbohydrate is a sugar or sugar alcohol.

26. (Currently amended) The ~~powder~~ compositions of claim 24, wherein said amino acid is a hydrophobic amino acid.

27. (Currently amended) The ~~powder~~ composition of claim 23, wherein said excipient said excipient is selected from the group consisting of citrate salts, leucine, raffinose, zinc salts, and combinations thereof.

28. (Currently amended) The ~~powder~~ composition of claim 23, wherein said excipient is a buffer.

29. (Currently amended) The ~~powder~~ composition of claim 23, wherein said excipient is a divalent metal cation.

30. (Currently amended) The ~~powder~~ composition of claim 1, characterized by an emitted dose of at least 30%.

31. (Currently amended) The ~~powder~~ composition of claim 30, characterized by an emitted dose of at least 45%.

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32. (Currently amended) The ~~powder~~ composition of claim 31, characterized by an emitted dose of at least 60%.

33. (Currently amended) The ~~powder~~ composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 10 microns.

34. (Currently amended) The ~~powder~~ composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 5 microns.

35. (Currently amended) The ~~powder~~ composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 3.5 microns.

36. (Currently amended) The ~~powder~~ composition of claim 1, comprising particles having a mass median diameter (MMAD) of between about 0.1 to 3 microns.

37. (Currently amended) The ~~powder~~ composition of claim 1, wherein the residual moisture content is less than about 10% by weight.

38. (Currently amended) The ~~powder~~ composition of claim 37, having a residual moisture content of less than about 5% by weight.

39. (Currently amended) The ~~powder~~ composition of claim 1, wherein said composition has a bulk density ranging from about 0.1-10 g/cc.

40. (Original) The powder composition of claim 1, in a unit dosage form.

41. (Withdrawn) A method for aerosolizing an IL-4R dry powder composition, said method comprising: (a) providing an IL-4R composition of claim 1, and (b) dispersing said composition into a gas stream to form an aerosolized dry powder suitable for inhalation.

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42. (Withdrawn) The method of claim 41, wherein said dispersing is achieved by means of a dry powder inhaler.

43. (Withdrawn) A method for preparing a dry IL-4R powder composition, said method comprising: (a) preparing a mixture or a solution of IL-4R in a solvent, and (b) spray-drying the mixture or solution to obtain the IL-4R powder of claim 1.

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